



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,845	03/30/2004	Stephen D. Pacetti	50623.00343	6042

7590

02/09/2006

Squire, Sanders & Dempsey L.L.P.  
Suite 300  
1 Maritime Plaza  
San Francisco, CA 94111

EXAMINER
----------

EDWARDS, LAURA ESTELLE

ART UNIT	PAPER NUMBER
----------	--------------

1734

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

5

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,845	<b>Applicant(s)</b> PACETTI, STEPHEN D.	
	<b>Examiner</b> Laura Edwards	<b>Art Unit</b> 1734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24,27 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24,27 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 7-9, 11, 15-17, 19, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) in view of Sass (US 6,383,215) for reasons set forth in the previous office action.

Claims 2, 10, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) in view of Sass (US 6,383,215) as applied to claims 1, 9, and 17 above and further in view of Vaartstra et al (US 6,435,798) for reasons set forth in the previous office action.

Claims 4, 12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) and Sass (US 6,383,215) as applied to claims 1, 9, and 17 above, and further in view of Vallana et al (US 5,370,684) for reasons cited in the previous office action.

Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) and Sass (US 6,383,215) as applied to claims 9 and 17 above, and further in view of Leidner et al (US 6,056,993) for reasons cited in the previous office action.

Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) and Sass (US 6,383,215) as applied to claims 1 and 9 above, and further in view of Bergmann (US 5,855,684) for reasons set forth in the previous office action.

Claims 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shim et al (US 6,372,283) in view of Sass (US 6,383,215) and Vaartstra et al (US 6,244,575).

Shim et al teach an apparatus for coating implantable devices comprising a CVD (chemical vapor deposition) coating chamber (12) connected to at least one source of coating material, and a pressure controller (34) in communication with the chamber wherein the apparatus enables a gaseous coating composition to be deposited on an implantable device at a desired pressure (see col. 5. lines 7-8). Shim et al are silent concerning the chamber being capable of coating the implantable device with a solvent based liquid coating composition via a spray applicator. However, it was known in the art, at the time the invention was made, to coat an implantable device with a vaporized solvent based liquid coating composition using a CVD type coating chamber as evidenced by Sass (see col.5, lines 59 to col. 6, line 25). Even though Sass recognizes that the solvent based liquid coating composition is applied in vaporized form, it is also well established in the CVD art to use a showerhead or atomizer in communication with a temperature controlled vaporizer so as to enable unvaporized or liquid coating composition to be applied on the substrate as evidenced by Vaartstra et al (see col. 7, lines 36-45 and col. 8, lines 59 to col. 9, lines 1-6). In light of the teachings of Shim et al, Sass, and Vaartstra et al, it would have been obvious to one of ordinary skill in the art seeking to minimize processing time, to utilize the Shim et al CVD apparatus for gas/vapor or liquid deposition of a desired stent coating

Art Unit: 1734

composition via incorporating into the CVD chamber, a showerhead or atomizer in communication with a temperature controlled vaporizer in order to allow gas/vapor or liquid coating of the stent in a single apparatus. The use of a spraying applicator or showerhead system in the Shim et al chamber to evenly distribute or spread a liquid coating composition about the surface of the implant device is within the purview of one skilled in the art. As for the recitation of the pressure controller controlling pressure in the coating chamber based on a given solvent, this recitation has been given no patentable weight because controlling of the pressure within the chamber based on the solvent used in the coating composition is deemed a user manipulative step. As recognized by Shim et al, controlling of the pressure within the CVD chamber to control characteristics of the coating film (see col. 5, lines 2-4) is well established such that it is within the purview of one skilled in the art to vary and control the pressure in the coating chamber in accordance with coating composition including solvent used therein in order to control coating film characteristics on the implantable device.

Claims 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMillan et al (US 5,316,579) in view of Schwarz et al (US 6,368,658).

McMillan et al teach a combination apparatus which enables gas/liquid deposition of a coating composition on a substrate comprising a chamber in which a liquid solvent based coating composition can be applied to a substrate disposed within the chamber (302), an applicator or turbine mist generator (304) for spraying liquid mist at the substrate, and a pressure controller (346, MFC) for controlling pressure in the chamber, the chamber capable of being operating in the pressure range of 1-7000 torr (see col. 15, lines 26 to col. 16, lines 56). McMillan et al are

Art Unit: 1734

silent concerning the apparatus being capable of coating an implantable device using a liquid solvent based coating composition. However, it was known in the coating art, at the time the invention was made, to coat a stent or implantable device with a liquid solvent based coating material or even a gaseous coating composition using a single coater equipped for handling several coating techniques (CVD to non-CVD application) as evidenced by Schwarz et al (see col. 12, lines 56-61). In light of the use of a single coater to be equipped so as to allow for multiple types of treatment to result on an implant device as evidenced by Schwarz et al, one of ordinary skill in the art would expect to use any known and conventional coating device such as taught by McMillan et al to coat the stent because the McMillan et al coating equipment allows for liquid deposition or vapor (CVD) deposition of a solvent based coating material on a substrate. The use of a single coater such as that to McMillan et al, to coat a stent with a desired coating composition liquid or gaseous using a variety of techniques in said single coater as taught by Schwarz et al, would lower manufacturing costs because separate equipment would not be required and processing time would be cut down due to plural coating processes being completed upon the implant device in the same chamber. As for the recitation of the pressure controller controlling pressure in the coating chamber based on a given solvent, this recitation has been given no patentable weight because controlling of the pressure within the chamber based on the solvent used in the coating composition is deemed a user manipulative step and the apparatus as defined by the combination above can be used in the claimed range of greater than or less than 760 torr.

***Response to Argument***

Art Unit: 1734

Applicant's argument filed 11/21/05 has been fully considered but is not persuasive.

Applicant contends that all rejections under 35USC 103 based on Shim et al and Sass should be dropped because of 112 sixth paragraph in that the prior art to Shim et al and Sass are directed to applying a vapor phase of a composition to a substrate and not a liquid phase of a composition. This argument is not deemed persuasive because Applicant's claimed invention does not exclude the solvent being applied in a vapor phase or form. Sass provides supporting evidence that the routineer in the art knows that a stent can be coated with a liquid solvent based coating composition wherein the composition is applied to the stent with the solvent being in vapor form. In addition, the present claim language (i.e., claims 1, 9, and 17) can be broadly read such that all that is required is an application device or applying means because a clear and positive recitation of a source or supply of liquid coating composition comprising a coating solvent is not even required.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


Art Unit: 1734

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Laura Edwards  
Primary Examiner  
Art Unit 1734

Le  
February 6, 2006